

PART 3

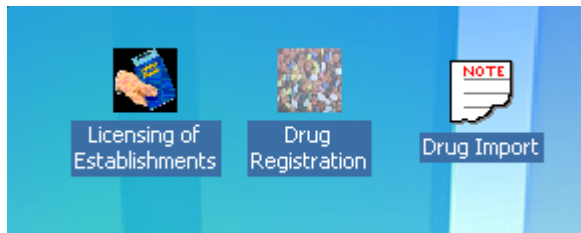
The remaining portion of this user manual is best used in conjunction with the installed “DRUG REGISTRATION AND INFORMATION SYSTEM”.

Before one can use any of the installed systems, ensure that your computer has been booted up. Otherwise, perform the following steps:


1. Turn on your computer.

At this time, your computer must be connected physically to a power outlet. Depending on how your system was installed, you may be asked to enter a network password or a windows desktop password.

2. At the Windows95™ or 98 Windows98™ desktop windows, you will find three (3) icons. These are the three subsystems in the computerized drug registration and information system.
3. Click the icon for the system you want to use.



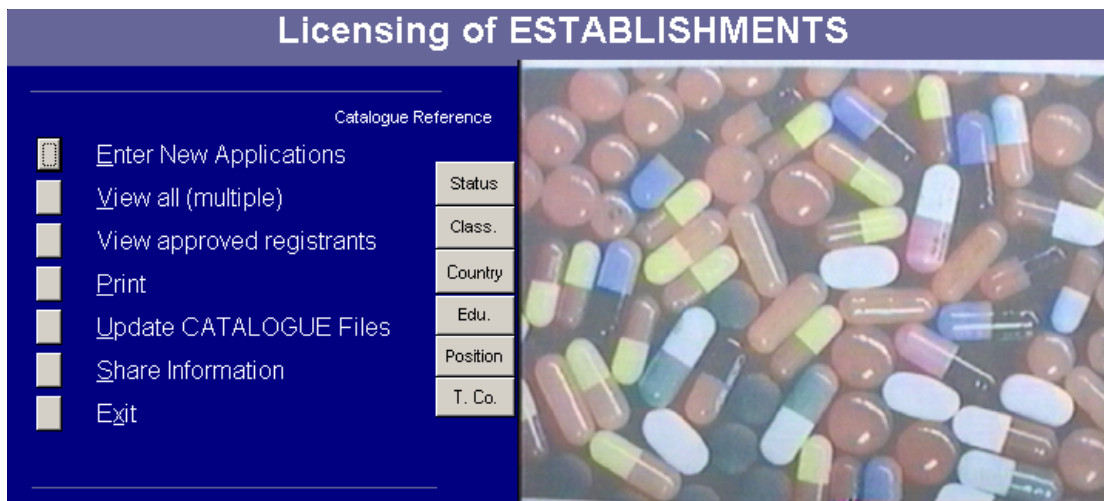
LICENSING OF ESTABLISHMENTS SUBSYSTEM

Double clicking the Licensing of Establishments shortcut icon  will load the Microsoft Access2000™ program and subsequently load the **Licensing of Establishments System** from within the Access 2000™ environment. The Licensing of Establishment System main menu will open. The licensing of establishments system contains the list of registered establishments transacting pharmaceutical products in the country. These establishments may be importers, agents, manufacturers, exporters,

repacking companies, pharmacy outlets and donors. After an evaluation of the activities of these establishments, and presuming that the establishment passes the minimum standards set for registration of an establishment, a regulatory authority issues a license to operate (LTO) certificate for that establishment. The list of registered establishments is “shared” information with the product registration (see below) and the drug import monitoring (see below) systems.

Essentially, each product has a license holder or owner who is the applicant of a product being registered in the product registration system. If an applicant is not registered, then the product registration system cannot accept the product application data that is being entered because the applicant company is not already a registered company and therefore will not be found in the system.

Shown below is the Licensing of Establishments System’s main menu with the various activity choices.



Menu	Explanation
1. Enter New Applications	Select this menu selection button to enter a new LTO application or to search and view existing establishments data records. A single form is presented on the screen. Use the filtering technique to search or to set the conditions of the search.
2. View all (multiple)	All LTO application records are shown in spreadsheet format.
3. View approved registrants	Various submenu choices for approved registrants will be shown. Approved registrants are based on the condition that the LTO # field in the dataset is not empty or left blank, indicating that the establishment has an existing LTO # assigned. The list of approved registrants does not consider whether the LTO license has expired.
4. Print	This selection button allows you to print the LTO certificate / license, a generic letter or a copy of an LTO sample application form.
5. Update catalogue Files	This menu selection button will be used for maintaining the data in catalogue files. Additions and/or corrections made on the catalogue files will immediately be reflected in the database records. The descriptions of catalogue files can be changed.
6. Share Information	Once new LTO applications are entered, the new data only resides in the Licensing of Establishments System database. The most recent record updates are only shared with the product registration system once this selection button is pressed. Sharing replaces the old licensing of establishments subset records that was last copied into the product registration system database.
7. Exit	This button closes all forms and exits the Licensing of Establishments System.

1. ENTERING A NEW APPLICATION

1. This form presents single documents of all the LTO applicants in the Licensing of Establishments System. Press the navigation buttons to the right (▶) or to the left (◀) to move records forward or backward. Press ⏪ to go to the first record on file (based on the sorted field) or ⏩ to go to the last record.

Edit / Add New Establishments

LTO Application No. Edit

Company INFORMATION		Contact Person INFORMATION			
Name of Company	3M SANTE	Contact Person	Francisco Sante		
Classification	PHARMACY*	Date of Birth	23/12/2002		
Type	MULTINATIONAL	Address	CONTACT ADDRESS		
Address	3M SANTE ADDRESS	District/ State	contact district/ state		
District	3m sante district	Position	DIRECTOR		
District / Province	3m sante province	Education	MASTERS IN BUSINESS ADMINISTRATI		
Country	FRANCE	University	UNIVERSITY OF CONTACT		
Zip Code	12345	Date Graduated	23/12/2002		
Telephone	234-2345	Years in service	5		
Fax	333-4565	LTO STATUS			
email	3MSANTE@GOV.FR	LTO#	LTO444444		
URL	WWW.3MSANTE.COM	Date registered	23/12/2002		
Registration History		Expiration	23/12/2003		
<table border="1"> <thead> <tr> <th>Date</th> </tr> </thead> <tbody> <tr> <td> </td> </tr> </tbody> </table>		Date		Status	PRINT LTO*
Date					
Record: ⏪ ⏩		Update LTO History			
Record: 1 of 492					

2. To enter a new application, press ">*" on the bottom of the form. A blank form is presented.
3. Using the application form, enter the data contained on the form, starting with a unique LTO application number.
4. After data entry, close the form by clicking on the "x" button on the top right of the open form.

2. VIEW ALL (MULTIPLE)

Applicant #	Company Name (Applic)	LTO# issued	Date registered	Expiration	Status / Activity	Classification	Type of Com
474	BASINS INTERNATIONAL		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
69	BYK GULDEN		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
68	BURAPHA		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
67	BROWN AND BURK		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
66	BRISTOL MYERS SQUIBB		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
65	BOUCHARA		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
64	BORYUNG BIOPHARM		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
63	BORDEN CO PTY LTD		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
62	BOEHRINGER INGELHEIM (FRANCE)		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
61	BOEHRINGER INGELHEIM		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
60	BLUE CROSS LABO		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
59	BIOSTAR		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
58	BIORGA		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
57	BIOPHELIA		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
56	BIOLOGIQUE (FRANCE)		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
55	BIOLOGIQUE		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL
54	BIOCODEX		23/12/2002	23/12/2003	NEW APPLICAT	FOREIGN COMPANY M ^a	MULTINATIONAL

Clicking on the View all (multiple) button presents all the LTO applications in spreadsheet format. The data of all product records are shown on your screen in a spreadsheet format.

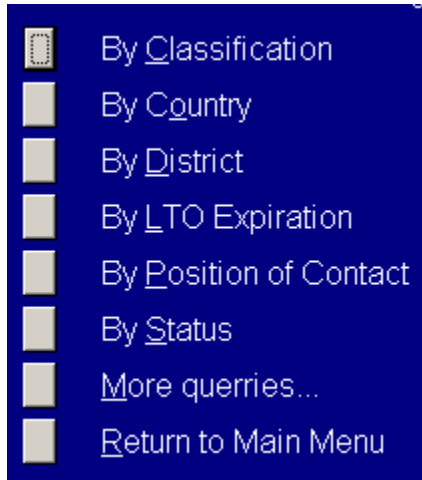
Each row represents one product on file and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).

Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one full screen up or down at a time.

Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).

To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3. VIEW APPROVED REGISTRANTS



This submenu is a selection of all approved registrants regardless of whether or not the LTO licenses are expired. The registration # field of all approved registrants are assumed to contain a registration # which is tagged by the system as having an existing license.

3.1 By Classification

Pressing the “By classification” button displays all approved applications arranged by Classification type. (i.e. agents, donors, distributors, exporters, importers, manufacturers, and pharmacies).

Use the filtering techniques discussed earlier to extract the desired classification type.

By Classification : Select Query						
	Classification	Applica	Company Name (Applic)	Contact Person	LTO# issued	Date registered
▶	PHARMACY*	1	3M SANTE	SANTE FRANCE	LTO444444	23/12/2002

3.2 By Country

Pressing this button displays all the applicants with APPROVED LTOs arranged by their country of origin.

Use the filtering technique to extract the applicants according to their country.

By Country : Select Query							
Country (Applic)	Applica	Company Name (Applic)	Type of Company	Contact Person	LTO# issued	Date registered	Expiration
FRANCE	1	3M SANTE	MULTINATIONAL	SANTE FRANCE	LTO444444	23/12/2002	23/12/200

3.3 By District

Pressing this button displays all the applicants with APPROVED LTOs arranged by the district.

Use the filtering technique to extract the Applicants according to district.

By District : Select Query						
District (Applic)	Applica	Company Name (Applic)	Classification	Type of Company	Street (Applic)	District (Applic)
3m sante district	1	3M SANTE	PHARMACY*	MULTINATIONAL	3M SANTE ADRE	3m sante district

3.4 By LTO Expiration

Pressing this button displays all the applicants with APPROVED LTOs sorted by the LTO expiration dates.

Again, use the filtering techniques to extract the desired applicants by their expiration dates.

By LTO Expiration : Select Query						
Expiration	Applica	Company Name (Applic)	Type of Company	Contact Person	LTO	
23/12/2003	1	3M SANTE	MULTINATIONAL	SANTE FRANCE	LTO44	

3.5 By Position of Contact

Pressing this button displays all the applicants with APPROVED LTOs sorted by the position of the contact person in the company.

Again, use the filtering techniques to extract the desired applicants by their positions in the company.

By Position of Contact : Select Query						
Position (Contac	Applica	Company Name (Applic)	Type of Company	Contact Person	L	
DIRECTOR	1	3M SANTE	MULTINATIONAL	SANTE FRANCE	LTO	

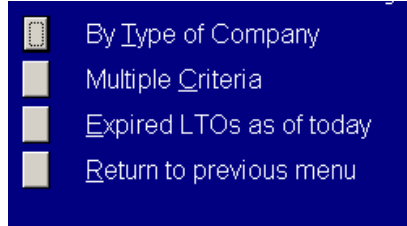
3.6 By status

Pressing this button displays all the applicants with APPROVED LTOs sorted by the status or activity tagged to the application.

Use the filtering techniques to extract the desired applicants according to the status or activity of the application.

By Status : Select Query						
Status / Activity	Applicat	Company Name (Applic)	Type of Company	Contact Person	LT	
▶ PRINT LTO*	1	3M SANTE	MULTINATIONAL	SANTE FRANCE	LTO4	

3.7 More Queries



3.7.1 By Type of Company

You can have another category for which to classify the establishments. An example of this is the classification of the pharmacy outlets based on what type of pharmaceutical products they can carry or the dispensing category they are allowed. The same may be true for the other establishments you issue a license for.

By type of company : Select Query						
Type of Company	Applica	Company Name (Applic)	Contact Person	LT		
▶ MULTINATIONAL	1	3M SANTE	SANTE FRANCE	LTO		

3.7.2 Multiple Criteria

This menu selection presents all the approved registrants in spreadsheet format. From the list presented, use the sorting and filtering technique in order to extract the desired records according to a set of conditions.

Applicant	Name of Company	Classification	Type of Company	Village	District	Country	Zip Code	Telep
1	ABBOTT	IMPORTER*	NATIONAL	BEAVERTON	AMA, EAST SE	UNITED STATES OF AMERICA	789000	(856) 21-
2	ACE	DONOR	SUBSIDIARY	PORTLAND	BAIMJURU, GULU	UNITED STATES OF AMERICA	56789	(856) 21-
3	AD-DRUGSTEL	DONOR	SUBSIDIARY	WASHINGTON	CAPE GLOUST	UNITED ARAB EMIRATES	567898	4545454
4	ADENPHAR	IMPORTER*	SUBSIDIARY	DOWNING	DARU, WESTE	SAINT KITTS AND NEVIS	45678	45678988
5	AHESCOOR	EXPORTER*	PLANT A	FOOTHILL	ERAVE, SOUTI	ANGOLA	3434333	2343232
6	ALDENT	DONOR	PLANT A	BERKSHIRE	FINSCHAFEN, I	PAKISTAN	5676878	(53) 7-21
7	ALDRIL	MANUFACTURER*	PLANT A	LANEWOOD	FINSCHAFEN, I	OMAN	7777777	(66) 2-29
8	ALLIED PHARM	EXPORTER*	PLANT A	BERSHIRE	ABAU, CENTR	ICELAND	6788	(856) 21-
9	ALTERMED	EXPORTER*	PLANT A	BARNES	AMA, EAST SE	FEDERATED STATES OF MICRONESIA	8999999	9999999
10	AM-EUROPHARMA	EXPORTER*	PLANT A	BEAVERTON	BAIMJURU, GULU	UNITED STATES OF AMERICA	5678909	(856) 21-
11	ASTA MEDICA	EXPORTER*	PLANT A	BEAVERTON	CAPE GLOUST	UNITED ARAB EMIRATES	34009	(33)04 67
12	AVENTIS PASTEUR	EXPORTER*	PLANT A	BEAVERTON	DARU, WESTE	TAMWAN, CHINA	10310	(66) 2-51
14	BAUSCH & LOMB	EXPORTER*	PLANT A	WASHINGTON	FINSCHAFEN, I	TAMWAN, CHINA	5961	856-21-2
15	BAXTER HEALTHCARE	EXPORTER*	PLANT A	DOWNING	FINSCHAFEN, I	TAMWAN, CHINA	69379	(33) 7877
16	BAYER	EXPORTER*	SUBSIDIARY	FOOTHILL	ABAU, CENTR	TAMWAN, CHINA	64293	(496)151-
17	BENECCOR	EXPORTER*	SUBSIDIARY	BERKSHIRE	AMA, EAST SE	TAMWAN, CHINA	400001	(91) 80-2
18	BIOGENICS	EXPORTER*	SUBSIDIARY	LANEWOOD	BAIMJURU, GULU	TAMWAN, CHINA		
19	BIONAX	DONOR	SUBSIDIARY	BERSHIRE	CAPE GLOUST	TAMWAN, CHINA	69379	(33) 4-72
20	BIOSIS	DONOR	SUBSIDIARY	BARNES	DARU, WESTE	TAMWAN, CHINA	10400	(66) 2-27
21	BIOTECH	DONOR	SUBSIDIARY	BEAVERTON	ERAVE, SOUTI	TAMWAN, CHINA		(856) 21-
22	BLOOMING FIELDS	DONOR	SUBSIDIARY	BEAVERTON	FINSCHAFEN, I	TAMWAN, CHINA	10260	(66) 2-31

3.7.3 Expired LTOs as of Today

This selection lists all APPROVED licenses that are expired as of the computer's system date. Make sure that the computer's clock is set on the correct day or the result of this query may be erroneous.

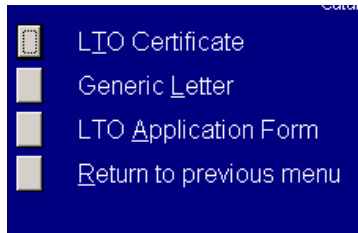
Expiration	Appl#	Name of Company	Classification	Type of Company	District	Country	Co
	59	HARVEY	IMPORTER*	SUBSIDIARY	LAKE MURRAY, WESTE	Malaysia	W
31/1/2/2001	55	FOURNIER	AGENT*	SUBSIDIARY	THUJ, GULF	France	WINNINGER
31/1/2/2001	80	LEYDEN	PHARMACY*	PLANT A	MALALALUA, GULF	PAKISTAN	WINNINGER
01/1/1/2002	117	COMPANY A (REVISED)	DISTRIBUTOR	MULTINATIONAL	DARU, WESTERN	DEMOCRATIC PEOPLE'S REPUBLIC	WARNER L
25/1/0/2002	115	MY NEW PHARMACY	PHARMACY*	NATIONAL	KABMUM, MOROBE	REPUBLIC OF KOREA	WARNER
	3	AD-DRUGSTEL	DONOR	SUBSIDIARY	CAPE GLOUSTER, VVN B	UNITED ARAB EMIRATES	WARD
	106	MYRA	PHARMACY*	MOTHER COMPANY	MENYAMYA, MOROBE	KAZAKHSTAN	WARD
	76	LE JUMONT	EXPORTER*	PLANT A	TAPINI, CENTRAL PROVI	PAKISTAN	TURNER
	19	BIONAX	DONOR	SUBSIDIARY	CAPE GLOUSTER, VVN B	TAMWAN, CHINA	TURNER
	23	BOEHRINGER INGELHEIM	DONOR	SUBSIDIARY	FINSCHAFEN, MOROBE	TAMWAN, CHINA	STEINBERG

3.7.4 Return to previous menu

This selection takes you back to the previous menu selection.

4. PRINT

The printing submenu opens a set of printing selections. Below is the list of printing options:

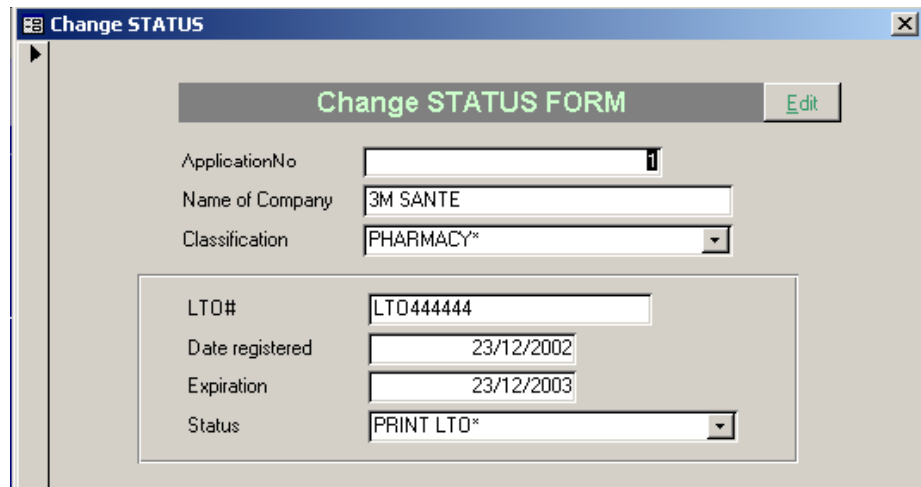


4.1 LTO Certificate

This selection allows you to prepare and automate printing of LTO Certificates. Selecting this option opens the submenu below. Follow through steps 1 and 2 to automate the printing of the certificates.

4.1.1 Step 1: Set appropriate status

Selecting this option opens the “Change Status” form as shown below.



A screenshot of a web-based form titled "Change STATUS". The form has a header bar with the title "Change STATUS FORM" and an "Edit" button. Below the header, there are several input fields and dropdown menus. The fields are: "ApplicationNo" (empty), "Name of Company" (3M SANTE), "Classification" (PHARMACY*), "LTO#" (LTO444444), "Date registered" (23/12/2002), "Expiration" (23/12/2003), and "Status" (PRINT LTO*). The form is enclosed in a light gray border.

Position the cursor on the “Status” field on the form and double click the left mouse button. All the field color changes to green, indicating that data in the fields can be changed. Please see below:

LTO#	LTO444444
Date registered	23/12/2002
Expiration	23/12/2003
Status	PRINT LTO*

Change the “status” field to “PRINT LTO*.”

Go to the next record and follow the same procedure above for the rest of the applications for which you want to print an LTO Certificate. After you have changed the status field of all the records you want to print certificates for, close the “change status form.” Proceed to Step 2.

4.1.2 Step 2: Print LTO



Making this selection will open a submenu. The submenu allows you to choose the certificate type you wish to print. For example, you want to print an agent’s LTO certificate,; two conditions must be met: a) the agent’s STATUS field must first be set to “PRINT LTO*”; b) the establishment’s classification must be that of an agent. Unless these two conditions are met, the LTO certificate for that agent will not be printed. The same is true for the rest of the other establishments such as an importer or manufacturer.

4.1.3 Print [Agents/Exporters/Importers/Manufacturers/Pharmacies] LTO

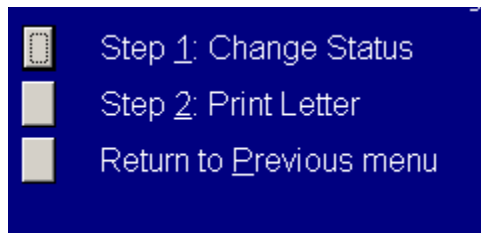
This selection will start the merging of the licensing of establishments data for the desired establishments for which you wish to print an LTO certificate. The data is merged into a template document. The certificates are now ready for printing in *MSWord™*.

4.1.4 Return to Previous menu

This selection takes you back to the previous menu selection.

4.2 Generic Letter

This selection allows you to prepare and automate printing of a Generic Letter you can later send to establishments that are listed in the Licensing of Establishments database. Selecting this option opens the submenu below. Follow steps 1 and 2 to automate the printing of the generic letter.



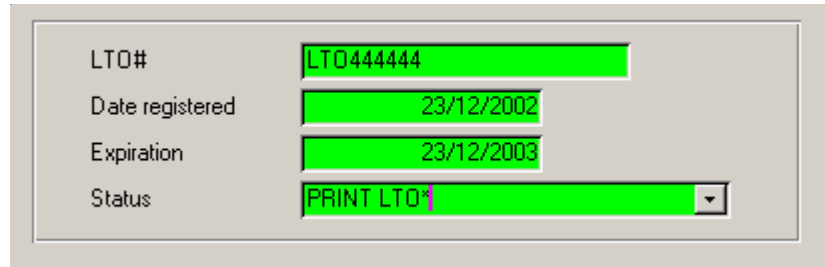
4.2.1 Step 1: Set appropriate status

Selecting this option opens the “Change Status” form as shown below.

A screenshot of a software window titled "Change STATUS". The window contains a form with the following fields and values:

Change STATUS FORM		Edit
ApplicationNo	<input type="text" value="1"/>	
Name of Company	<input type="text" value="3M SANTE"/>	
Classification	<input type="text" value="PHARMACY*"/>	
LTO#	<input type="text" value="LTO444444"/>	
Date registered	<input type="text" value="23/12/2002"/>	
Expiration	<input type="text" value="23/12/2003"/>	
Status	<input type="text" value="PRINT LTO*"/>	

Position the cursor on the “Status” field on the form and double click the left mouse button. All the field color changes to green, indicating that data in the fields can be changed. Please see below:



The screenshot shows a form with four fields, all highlighted in green. The fields are: LTO# (LTO444444), Date registered (23/12/2002), Expiration (23/12/2003), and Status (PRINT LTO*). The Status field is a dropdown menu.

LTO#	LTO444444
Date registered	23/12/2002
Expiration	23/12/2003
Status	PRINT LTO*

Change the “status” field to “Write letter*.”

Go to the next record and follow the same procedure above for the rest of the applications for which you want to print an LTO Certificate. After you have changed the status field of all the records you want to print certificates for, close the “change status form.” Proceed to Step 2 below.

4.2.2 Step 2: Print letter

The submenu will start the merging process in order to start printing the generic letter. Take note that the STATUS field must first be set to “WRITE LETTER*”

4.2.3 Return to Previous Menu

This selection takes you back to the previous menu selection.

4.3 LTO application form

This option will print an LTO application form.

4.4 Return to Previous Menu

This selection takes you back to the previous menu selection.

5. UPDATE CATALOGUE FILES

This option will open the CATALOGUE file tables. There are six CATALOGUE tables in the licensing of establishments system: 1) Activity; 2) Classification; 3) Country; 4) Education; 5) Position; and 6) Type of Company.

Type	Activity
3	EXPIRED
5	LTO FOR SIGNATURE
4	NEW APPLICATION
2	PRINT LTO*
7	UNDER EVALUATION
6	WITHDRAWN
1	WRITE LETTER*
*	mber)

To enter a new catalogue item, select the catalogue file tab. In the example above, the activity catalogue file is displayed. To enter a new item, click on the ►* icon below the form. Enter the new item in the blank row. Close the form after entering the item or items by clicking the ✕ icon on the top right of the form.


6. SHARE INFORMATION

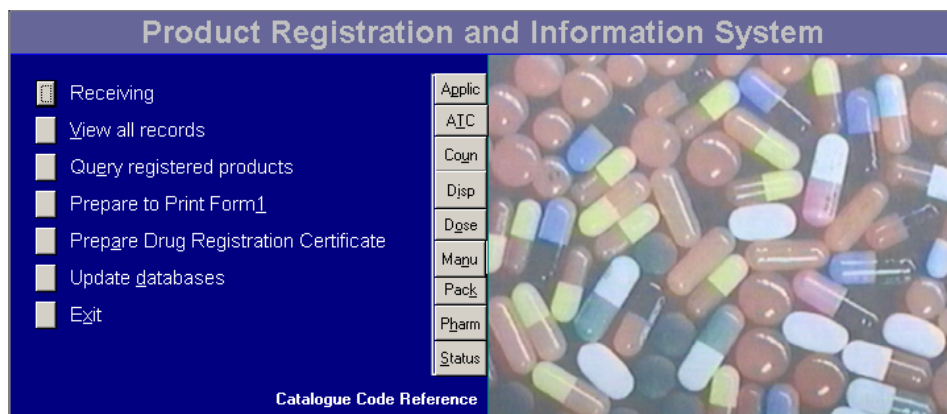
Sharing the information selection will copy a subset of the list of establishments records into the product registration database. This essentially overwrites the old licensing of establishments records that was last shared with the product registration system with the most recent recordset.

7. EXIT

This closes all windows and subsequently closes all databases and then quits the application system.

PRODUCT REGISTRATION SYSTEM

To activate the product registration system, double click the  icon on your windows desktop. The product registration system MAIN MENU is presented as shown below.



To select an item (e.g. View all records), move the mouse pointer to the selection you wish and then double click the left button. Each item in the selection has an underlined letter. You can use this as a keyboard shortcut to call up the underlying submenu. For example in **View records**, the letter V is underlined so you can simply press V on the keyboard to activate the selection.

The product registration system is an application system that keeps track of drug product applications for drug registration. Basic information such as registered products can be retrieved and various reports printed as needed. Reports can be printed using *MSWord*[™] or *MSEXcel*[™]. Printing of the product registration certificate is automated.

THE PRODUCT REGISTRATION SYSTEM

1. RECEIVING

The screenshot shows a software window titled "Receiving New Product Application". It contains the following fields and controls:

- Application No: [Empty text box]
- Applicant / MA Holder: [3M SANTE (dropdown menu)]
- Manufacturer: [3M SANTE (dropdown menu)]
- Brand Name: [ASPIRINE PH 8TM 500MG (text box)]
- Dosage Form: [Empty dropdown menu]
- Applied: [23/12/2002 (text box)]
- [Print Acknowledgement button]
- Record: [Navigation icons] 1 [Navigation icons] of 4682

Choose this menu selection to do the following:

- o To enter new PRODUCT APPLICATIONS into the drug registration system database
- o To print an acknowledgement receipt for the product applications
- o To print a routing slip document to be attached to the dossier for product applications
- o To print routine reports on product applications received on a specified time frame/s, arranged by applicant or marketing authorization holder, by name of Manufacturer or by pharmaceutical dosage format of the products. The general layout of the report can be designed by user preference with the use of the *MSWord™* or *MSExcel™* office suite programs. It is assumed that the user is familiar with either using the *MSWord* and/or *MSExcel* applications.
 1. At this stage, it is presumed that you have examined all the items on the application form and that the entries have been completed.
 2. On the “*Product Registration System*” MAIN MENU, double click on the ‘RECEIVING’ button.

3. The “Receiving New Product Application” window opens.
4. To add a new application, click the “>*” button found on the bottom of the receiving window or the same button that is found on the drug registration system menu bar.
5. A blank form opens (the cursor is positioned on the Application number field).
6. There are 6 items you will need to enter:
 - a. Application number;
 - b. Applicant name;
 - c. Name of manufacturer;
 - d. Brand name / trade name;
 - e. Dosage form; and
 - f. Date of application.
7. Enter a unique application number on the application number field.
8. From the product application form that was submitted, enter the required data.
9. At the end of the data entry process, move the records forward or backward by pressing “>” or “<” to save the data you just entered.
10. To print an acknowledgement receipt and routing slip document for each of the applications you just entered, press the “Print Acknowledgement” button.
11. A dialogue box opens.
12. On the “Enter begin #” field, enter the application # of the product application where you want to begin the printing of the acknowledgement receipt and/or routing slip.
13. Enter “OK”.
14. A second dialogue box appears.
15. On the “Enter end #” field, enter the application # from where you want to end printing.

16. After entering the “end #”, an *MSWord*[™] word processing document opens.
17. What you have in front of you is a *MSWord*[™] template.
18. Click on the “merge” icon on the drug registration menu bar.
19. A “merge” dialogue box opens.
20. You have a choice of where to print your document (a printer or another file).
21. After making your choice, click the “merge” button on the “Merge window ” dialogue box.

Note: If you chose the *MSWord*[™] document to be printed to another file instead of directly to a printer, the documents are presented on your screen and are now ready for printing.
22. Print the document as you would normally print an *MSWord*[™] document (by pressing the selections File-Print on the *MSWord*[™] program).
23. To close each window on your screen, click the “x” button found on the top right portion of each open window.

2. VIEW ALL RECORDS

Choose this menu selection to do the following:

- o To view product records in individualized forms (one record at a time)
- o To view product records in a spreadsheet format (several records at a time)
- o To search and find records using one several criteria
- o To print record data based on the set criteria
- o To print generic-type reports, based on set criteria, using *MSWord*[™] or *MSExcel*[™]

2.1 View individual record

- 2.1.1 The first product record on file is shown on the screen - the order will depend on the sorting order when the records were last saved.
- 2.1.2 The screen is divided in four distinct parts: product data; applicant holder data; manufacturer data and product status (shown as "Status"-button next to the Application # field).

Search the records based on the searching and filtering techniques (under the "Searching / Filtering Records" topic)

Product INFORMATION		License Owner INFORMATION	
Brand Name	ASPIRINE PH 8TM 500MG	Company Name	3M SANTE
INN	ASPIRINE PH 8TM 500MG	Classification	EXPORTER*
Dosage Form		Type Of Company	MULTINATIONAL
Storage		Address	3m sante address
Shelf Life		District	3m sante district
Primary Packaging		Province	3m sante province
Pack Size	8/5 X 10 CP.	Country	FRANCE
Dispensing Category	PRESCRIPTION ONLY	Zip code	12345
ATC Classification		Telephone	234-2345
PharmClass	ANALGESICS & ANTI-INFLAMMATORIES	Fax	333-4565
EDL?	<input checked="" type="checkbox"/>	Contact Person	sante france
Description	SDASDF	LTO#	lto444444
Country	FRANCE	DateRegistered	23/12/2002 18:20:38
Registration No (importing)	31/12/2002	Expiration	23/12/2003 18:20:38
Date of registration (importing)	23/12/2002	Product Manufacturer INFORMATION	
Ingredients	ASPIRINE PH 8TM 500MG	Name	3M SANTE
Indications	ASDFS	Street	123 RUE
Contraindications	ASDFS	Province	LYON
Side Effect	AFASD	Country	FRANCE
Unit price	88	Zip Code	123
Remarks		Telephone Number	111-2222
		Fax Number	222-3333

2.2 View multiple records

1. All data of all product records are shown on your screen in a spreadsheet format.
2. Each row represents one product on file and each column represents the data for that field item (e.g. application #, brand name, etc.)

3. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
4. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic)
5. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet

Product INFORMATION		License Owner INFORMATION	
Brand Name	ASPIRINE PH 8TM 500MG	Company Name	3M SANTE
INN	ASPIRINE PH 8TM 500MG	Classification	EXPORTER*
Dosage Form		Type Of Company	MULTINATIONAL
Storage		Address	3m sante address
Shelf Life		District	3m sante district
Primary Packaging		Province	3m sante province
Pack Size	B/5 X 10 CP.	Country	FRANCE
Dispensing Category	PRESCRIPTION ONLY	Zip code	12345
ATC Classification		Telephone	234-2345
PharmClass	ANALGESICS & ANTI-INFLAMMATORIES	Fax	333-4565
EDL?	<input checked="" type="checkbox"/>	Contact Person	sante france
Description	SDASDF	LTO#	lto444444
Country	FRANCE	DateRegistered	23/12/2002 18:20:38
Registration No (importing)	31/12/2002	Expiration	23/12/2003 18:20:38
Date of registration (importing)	23/12/2002	Product Manufacturer INFORMATION	
Ingredients	ASPIRINE PH 8TM 500MG	Name	3M SANTE
Indications	A5DFS	Street	123 RUE
Contraindications	A5DFS	Province	LYON
Side Effect	AFA5D	Country	FRANCE
Unit price	88	Zip Code	123
Remarks		Telephone Number	111-2222
		Fax Number	222-3333

2.3 Return to Main Menu

1. Clicking the “Return to Main Menu” button brings you back to the previous menu selection screen (The Drug Registration Main Menu).

3. QUERY REGISTERED PRODUCTS

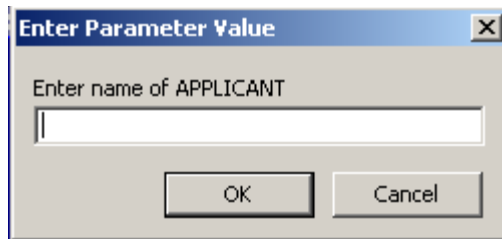
Choose this menu selection to do the following:

- o To view all registered product records in a spreadsheet format (several records at a time).
- o To search and find records of only registered products on file using one or multiple criteria.
- o To print record data based on the set criteria.
- o To print generic-type reports of registered products based on set criteria using *MSWord™* or *MSExcel™*.

NOTE: The system assumes all product applications have been approved when the REGISTRATION # field of the record is not empty.

3.1 Products by Applicant

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY APPLICANT” button.



2. Enter the name of the applicant as it was spelled exactly when it was entered in the database. If you are unsure of the spelling, make use of the wild card "*" symbol to represent any letter or group of letters in the dialogue box field.
3. Click the "OK" button to start the search process.

- The data of all APPROVED product records, in spreadsheet format, based on the applicant field criteria you have earlier specified is shown on the screen.

Application#	Applicant / MA Holder	Manufacturer	Brand / Trade Name	INN	Pharmaceutical
1	3M SANTE	3M SANTE	ASPIRINE PH 8TM 500MG	ASPIRINE PH 8TM 500MG	
3	A BAILLY SPEAB	A BAILLY SPEA	THEINOL SOL. BUY.	THEINOL SOL. BUY.	
2	A MENARINI	A MENARINI	MEGENTAL ® 80 MG	MEGENTAL ® 80 MG	
22	ABBOTT LABORATC	ABBOTT LABOF	ENSURE	ENSURE	
23	ABBOTT LABORATC	ABBOTT LABOF	ENSURE ®	ENSURE ®	
25	ABBOTT LABORATC	ABBOTT LABOF	FORANE ® 99.9% WWW	FORANE ® 99.9% WWW	
24	ABBOTT LABORATC	ABBOTT LABOF	FORANE ® 99.9% WWW	FORANE ® 99.9% WWW	
30	AEGIS LTD	AEGIS LTD	CIFEX ® 100MG/5ML	CIFEX ® 100MG/5ML	
29	AEGIS LTD	AEGIS LTD	CIFEX ® 100MG/5ML	CIFEX ® 100MG/5ML	
31	AEGIS LTD	AEGIS LTD	CLERON 125MG/5ML	CLERON 125MG/5ML	

- Each row represents one APPROVED product on file based on the applicant field criteria earlier set. Each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “**Searching / Filtering Records**” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.2 Products by Anatomical Therapeutic Chemical Classification Codes

- A dialogue box appears on the screen after clicking the “PRODUCTS BY ATC CODES” button.
- Enter the exact ATC Code of the product. If unsure of the code, then make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.

NOTE: A listing of ATC Codes is available in the CATALOGUE CODE REFERENCE found on the MAIN MENU. The code listing can be sorted by ATC codes or by the drug classification.

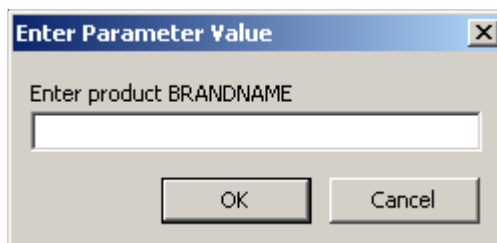
3. Click the “OK” button to start the search process.
4. The data of all APPROVED product records, in spreadsheet format, based on the ATC criteria you have earlier specified is shown on the screen.

Application#	Applicant / MA Holder	Manufacturer	Brand / Trade Name	INN	Pharmaceutical
1	3M SANTE	3M SANTE	ASPIRINE PH 8TM 500MG	ASPIRINE PH 8TM 500MG	
3	A BAILLY SPEAB	A BAILLY SPEA	THÉINOL SOL. BUV.	THÉINOL SOL. BUV.	
2	A MENARINI	A MENARINI	MEGENTAL ® 80 MG	MEGENTAL ® 80 MG	
22	ABBOTT LABORATC	ABBOTT LABOF	ENSURE	ENSURE	
23	ABBOTT LABORATC	ABBOTT LABOF	ENSURE ®	ENSURE ®	
25	ABBOTT LABORATC	ABBOTT LABOF	FORANE ® 99.9% WWW	FORANE ® 99.9% WWW	
24	ABBOTT LABORATC	ABBOTT LABOF	FORANE ® 99.9% WWW	FORANE ® 99.9% WWW	
30	AEGIS LTD	AEGIS LTD	CIFEX ® 100MG/5ML	CIFEX ® 100MG/5ML	
29	AEGIS LTD	AEGIS LTD	CIFEX ® 100MG/5ML	CIFEX ® 100MG/5ML	
31	AEGIS LTD	AEGIS LTD	CLERON 125MG/5ML	CLERON 125MG/5ML	

5. Each row represents one APPROVED product on file based on the ATC criteria earlier set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.3 Products by Brand Name

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY BRAND NAME” button.



2. Enter the exact BRAND NAME of the product. If unsure of the code, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.
3. Click the “OK” button to start the search process.

Product Registration - [Products by brandname : Select Query]					
Application#	Applicant / M	Brand / Trade Name	Manufacturer	INN	Pharmace
3474	SANOFI-WV	CA. CORBIERE-C 1000 DPP CP.	SANOFI-WINTHF	CA. CORBIERE-C 1000 DPP CP.	
3440	SANDOZ	CA-C 1000 SANDOZ ®	SANDOZ	CA-C 1000 SANDOZ ®	
3945	THAI NAKC	CADEXCIN - N EYE / EAR DROPS	THAI NAKORN F	CADEXCIN - N EYE / EAR DROPS	
2601	OLIC LTD	CALADRYL ® CREAM	OLIC LTD	CALADRYL ® CREAM	
2602	OLIC LTD	CALADRYL ® LOTION	OLIC LTD	CALADRYL ® LOTION	
3441	SANDOZ	CALCIBRONAT ® 2G COMP. EFFE	SANDOZ	CALCIBRONAT ® 2G COMP. EFFI	
3442	SANDOZ	CALCIBRONAT ® 0,124G I.V	SANDOZ	CALCIBRONAT ® 0,124G I.V	
3513	SANOFI SY	CALCIUM CORBIERE®	SANOFI SYNTHI	CALCIUM CORBIERE®	
3457	SANDOZ	CALCIUM SANDOZ	SANDOZ	CALCIUM SANDOZ	
3458	SANDOZ	CALCIUM SANDOZ FORTE 500MG	SANDOZ	CALCIUM SANDOZ FORTE 500MC	
2450	MEDICAP	CALCIVITA CAPS.	MEDICAP	CALCIVITA CAPS.	
3443	SANDOZ	CALMIXÈNE® SIROP	SANDOZ	CALMIXÈNE® SIROP	
1660	GLAXO (TH	CALPOL 500MG	GLAXO (THAILA	CALPOL 500MG	
1661	GLAXO (TH	CALPOL 6-12 SYRUP 250MG/5ML	GLAXO (THAILA	CALPOL 6-12 SYRUP 250MG/5M	
2666	PPM	CALTOUX® SIROP ADULTES 6,6 PPM		CALTOUX® SIROP ADULTES 6	
2667	PPM	CALTOUX® SIROP ENFANT 5MG PPM		CALTOUX® SIROP ENFANT 5M	
714	CADILA HE	CAMICIL 250 CAPS.	CADILA HEALTH	CAMICIL 250 CAPS.	
715	CADILA HE	CAMICIL 500 CAPS.	CADILA HEALTH	CAMICIL 500 CAPS.	
9	ANB LAB	CAMPHOR VIFORT INJ. 300MG/2M	ANB LAB	CAMPHOR VIFORT INJ. 300MG/2I	

4. The data of all APPROVED product records, in spreadsheet format, based on the Brand Name criteria you have specified is shown on the screen.
5. Each row represents one APPROVED product on file, based on the BRAND NAME criteria set, and each column representing the data for that field item (e.g. Application #, Brand Name, etc.).

6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full, up or down, at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.4 Products by Country

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY COUNTRY” button.

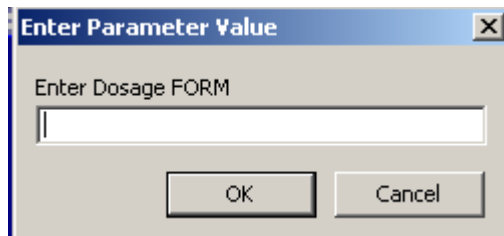
2. Enter the exact name of the country from where the product is manufactured or imported from. If unsure of the exact spelling of the country, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.
3. Click the “OK” button to start the search process.
4. The data of all APPROVED product records, in spreadsheet format, based on the name of country criteria you have specified is shown on the screen.

Product Registration - [Products accdg to country : Select Query]					
Application#	Applicant / M	Country of origin	Manufacturer	Brand / Trade Name	INN
3630	SIGMA PH/	AUSTRALIA	SIGMA PHARMA	LOGICIN COUGH MIXTURE FOR COI	LOGICIN COUGH MIXTURE FOR CC
2903	PFIZI	AUSTRALIA	PFIZER (AUS)	NORVASC* 5MG	NORVASC* 5MG
4679	RP SCHER	AUSTRALIA	RP SCHERER HC	GARLIC PEARLS	GARLIC PEARLS
3624	SIGMA PH/	AUSTRALIA	SIGMA PHARMA	GASTROGEL TABLETS	GASTROGEL TABLETS
3625	SIGMA PH/	AUSTRALIA	SIGMA PHARMA	GASTROGEL ORAL LIQUID	GASTROGEL ORAL LIQUID
3626	SIGMA PH/	AUSTRALIA	SIGMA PHARMA	GASTROGEL ORAL LIQUID 250MG-	GASTROGEL ORAL LIQUID 250MC
3764	STEPHEN F	AUSTRALIA	STEPHEN HUNTE	GASTROSTAT	GASTROSTAT
1737	HERRON	AUSTRALIA	HERRON	GOANNA HEAT CREAM	GOANNA HEAT CREAM
1738	HERRON	AUSTRALIA	HERRON	GOANNA HEAT CREAM	GOANNA HEAT CREAM
2794	PAN PHAR	AUSTRALIA	PAN PHARMA (GW COLD	GW COLD
1739	HERRON	AUSTRALIA	HERRON	HERRON PAR&CFT&MCI 500MG	HERRON PAR&CFT&MCI 500MG

5. Each row represents one approved product on file based on the name of the country criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full, up or down, at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.5 Products by Dosage Forms

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY DOSAGE FORMS” button.
2. Enter the exact name of the DOSAGE FORM of the product. If unsure of the exact spelling of the dosage form, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.



3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format, based on the dosage form criteria you have specified is shown on the screen.

Product Registration - [Products accdg to dosage forms : Select Query]						
Application#	Applicant / M	Pharmaceutical dosag	Manufacturer	Brand / Trade Name	INN	
532	BURAPHA	TABLET	BURAPHA	DIARA 2MG	DIARA 2MG	
633	CPE	TABLET	CPE	HALOPERIDOL CPE 5MG	HALOPERIDOL CPE 5MG	
3085	RANBAXY	TABLET	RANBAXY	ENHANCIN 375 TABLETS 250+125	ENHANCIN 375 TABLETS 250	
618	CPE	TABLET	CPE	DEXAMETHASONE 0.5MG CPE	DEXAMETHASONE 0.5MG CP	
617	CPE	TABLET	CPE	DEXAMETHASONE 0.5MG CPE	DEXAMETHASONE 0.5MG CP	
1728	HANMI PHA	TABLET	HANMI PHARMA	DERMATRIS® CREAM	DERMATRIS® CREAM	

5. Each row represents one approved product on file based on the dosage form criteria set, and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.6 Products by Manufacturer

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY MANUFACTURER” button.
2. Enter the exact name of the manufacturer of the products. If unsure of the exact spelling of the country, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.

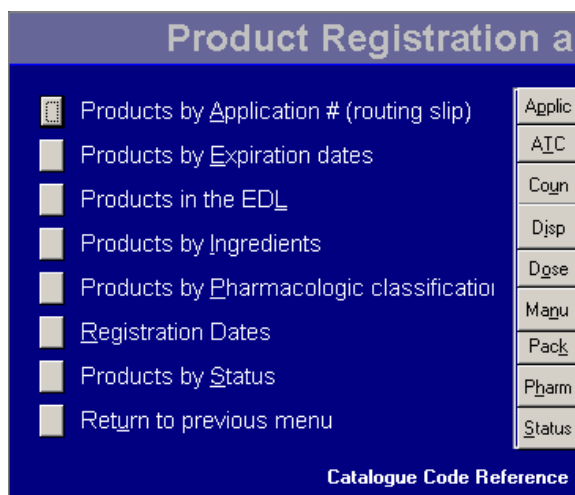
3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format, based on the Name of Manufacturer criteria you have specified is shown on the screen.

Product Registration - [Products accdg to manufacturer : Select Query]						
Applicat	Applicant / M	Manufacturer	Brand / Trade Name	INN	Pharmac	
3	A BAILLY :	A BAILLY SPEA	THÉINOL SOL. BUV.	THÉINOL SOL. BUV.		
2	A MENARIP	A MENARINI	MEGENTAL ® 80 MG	MEGENTAL ® 80 MG		
23	ABBOTT L.	ABBOTT LABOF	ENSURE ®	ENSURE ®		
22	ABBOTT L.	ABBOTT LABOF	ENSURE	ENSURE		
25	ABBOTT L.	ABBOTT LABOF	FORANE ® 99.9% VVVV	FORANE ® 99.9% VVVV		

5. Each row represents one approved product on file based on the name of the manufacturer criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time;
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic)
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7 More Queries

1. Clicking the “..... more Queries” button activates another set of Query buttons.
2. The ...more Queries menu appears on the screen.



3.7.1 Products by Application # (Routing Slip)

1. A dialogue box appears on the screen after clicking the “PRODUCTS BY APPLICATION # (Routing Slip)” button.
2. Enter two sets of numbers: a beginning number, the application number of the first in the range of records you wish to retrieve; and an end number, the last in the range of records you want to retrieve.

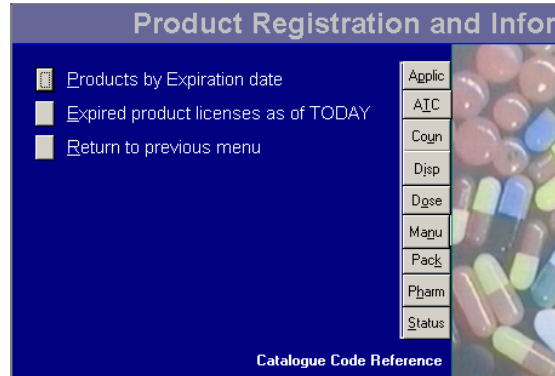
For example, if you wish to retrieve application numbers 1 through 100, the beginning number is 1 and the end number is 100. Enter the appropriate numbers.

3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format based on the application number ranged criteria you have specified is shown on the screen.

Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN	Pharm
5	AJC PHARI	AJC PHARMA	PARACETAMOL 500MG	PARACETAMOL 500MG	
6	ANB LAB	ANB LAB	A.N.B 100 COMPLEX	A.N.B 100 COMPLEX	
7	ANB LAB	ANB LAB	AMPAVIT 1000MCG INJ.	AMPAVIT 1000MCG INJ.	
8	ANB LAB	ANB LAB	ATROPINE SULPHATE 1/100GR	ATROPINE SULPHATE 1/100GR	
9	ANB LAB	ANB LAB	CAMPHOR VIFORT INJ. 300MG/2M	CAMPHOR VIFORT INJ. 300MG/2I	
10	ANB LAB	ANB LAB	CHLORAMPHENICOL (250MG+30M	CHLORAMPHENICOL (250MG+30M	
11	ANB LAB	ANB LAB	DEXTROSE 10 % IN DISTILLED Ww	DEXTROSE 10 % IN DISTILLED Ww	INFUSI
12	ANB LAB	ANB LAB	DEXTROSE 5 % IN DISTILLED Ww	DEXTROSE 5 % IN DISTILLED Ww	INFUSI
13	ANB LAB	ANB LAB	DEXTROSE 5% + 0,9% NORMAL S	DEXTROSE 5% + 0,9% NORMAL :	
14	ANB LAB	ANB LAB	DEXTROSE 5% + 1/2 NAACL	DEXTROSE 5% + 1/2 NAACL	
15	ANB LAB	ANB LAB	DEXTROSE 5% + 1/3 NAACL	DEXTROSE 5% + 1/3 NAACL	INFUSI
16	ANB LAB	ANB LAB	GLUCOSE 50% INJ.	GLUCOSE 50% INJ.	INFUSI
17	ANB LAB	ANB LAB	ISOTONIC SODIUM CHLORIDE 0,9 %	ISOTONIC SODIUM CHLORIDE 0,9 %	
18	ANB LAB	ANB LAB	LACTATED RINGER'S SOL. INJ.	LACTATED RINGER'S SOL. INJ.	
19	ANB LAB	ANB LAB	PYRIDOXINE HDROCHLORIDE 10C	PYRIDOXINE HDROCHLORIDE 1C	
20	ANB LAB	ANB LAB	QUININE DIHYDROCHLORIDE 600M	QUININE DIHYDROCHLORIDE 600M	
21	ANB LAB	ANB LAB	STERILE WATER FOR INJECTION	STERILE WATER FOR INJECTION	
22	ABBOTT L.	ABBOTT LABOF	ENSURE	ENSURE	

5. Each row represents one approved product on file based application number range criteria set, and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.2 Products by Expiration Dates



1. A dialogue box appears on the screen after clicking the “PRODUCTS BY EXPIRATION DATES” button.
2. You are expected to enter two dates – the beginning and ending dates that enclose the group or groups of approved product records based on the expiration date field.

(NOTE: Date format is of the form: dd/mm/yyyy)

3. Click the “OK” button to start the search process.

- The data of all approved product records, in spreadsheet format, based on the expiration dates criteria you have specified is shown on the screen;
- Each row represents one approved product on file based on the name of the expiration date criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).

Product Registration - [Products accdg to expiration dates : Select Query]

MA expirat	Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN
08/01/2000	438	BIOLOGIQL	BIOLOGIQUE (FI	ALOPLASTINE SIMPLE	ALOPLASTINE SIMPLE
08/01/2000	441	BIOLOGIQL	BIOLOGIQUE (FI	ANTEBOR B6 LOTION	ANTEBOR B6 LOTION
08/01/2000	439	BIOLOGIQL	BIOLOGIQUE (FI	ANTÉBOR LOTION	ANTÉBOR LOTION
08/01/2000	440	BIOLOGIQL	BIOLOGIQUE (FI	NEUROCALCIUM	NEUROCALCIUM
09/01/2000	3540	SCAT	SCAT	MUCOTHIOL 100MG	MUCOTHIOL 100MG
09/01/2000	3539	SCAT	SCAT	MUCOTHIOL 100MG	MUCOTHIOL 100MG
09/01/2000	3541	SCAT	SCAT	OZOTHINE À LA DIPROPHYLLINE IN	OZOTHINE À LA DIPROPHYLLII
09/01/2000	3542	SCAT	SCAT	OZOTHINE À LA DIPROPHYLLINE S	OZOTHINE À LA DIPROPHYLLII
09/01/2000	3543	SCAT	SCAT	OZOTHINE À LA DIPROPHYLLINE S	OZOTHINE À LA DIPROPHYLLII
09/01/2000	3544	SCAT	SCAT	OZOTHINE INJECTABLES	OZOTHINE INJECTABLES
09/01/2000	3546	SCAT	SCAT	OZOTHINE SUPP. ADULTES	OZOTHINE SUPP. ADULTES
10/01/2000	973	CLINMIDY	CLINMIDY	TRANXÈNE 10 MG	TRANXÈNE 10 MG
10/01/2000	3259	RHONE PO	RHONE POULEN	TERPINE GONNON 100MG + 5MG	TERPINE GONNON 100MG + 5I
10/01/2000	63	AGUETTAP	AGUETTANT	MANNITOL 20%	MANNITOL 20%
10/01/2000	4035	THERAMEX	THERAMEX	HEPTYLATE DE TESTOSTÉRON 2	HEPTYLATE DE TESTOSTÉRO
10/01/2000	974	CLINMIDY	CLINMIDY	TRANXÈNE 5MG	TRANXÈNE 5MG
10/01/2000	972	CLINMIDY	CLINMIDY	THIOPHÉNICOL 750MG/5ML	THIOPHÉNICOL 750MG/5ML
10/01/2000	971	CLINMIDY	CLINMIDY	THIOPHÉNICOL 250MG	THIOPHÉNICOL 250MG

- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.2.1 Products Expiring as of Today

- Activating the “Products Expiring as of Today” button displays, in spreadsheet format, the list of all approved application records in the database whose current registration certificates have expired as of the current date.

Product Registration - [Expired product licenses as of today : Select Query]

Application#	MA expirat	Brand / Trade Name	Pharmaceutical dosage form	Ingredients	MA registration #	Applicant / M
1262	25/12/2002	NAPAMIDE 2.5MG TABLET		NAPAMIDE 2.5M 01-1921		DOUGLAS
3659	25/12/2002	DEXTROSE 5% IN SALINE (DEXTROSE 5% I 00-1610		SINTONG C
3130	25/12/2002	ROSCILLIN® 1000MG INJ.		ROSCILLIN® 10 99-1165		RANBAXY
3135	25/12/2002	ROSCILOX® 500MG CAPS	CAPSULE	ROSCILOX® 50 99-1164		RANBAXY
3080	25/12/2002	CIFRAN 500MG		CIFRAN 500MG 99-1203		RANBAXY
3147	25/12/2002	TOBITIL 20 MG TABLETS		TOBITIL 20 MG 99-1163		RANBAXY
3090	25/12/2002	GRAMONEG® 500MG TAI		GRAMONEG® 5 99-1166		RANBAXY
2393	24/12/2002	TELFAST® BD 60MG		TELFAST® BI 00-1661		MARION &
614	23/12/2002	CIPROFLOXACIN 0,3% EYE EYE / EAR DROPS		CIPROFLOXACIN 98L-0013		CPE

- Each row represents one approved product on file and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.2.2 Return to Previous Menu

- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.
- Clicking the “Return to Main Menu” button brings you back to the previous menu selection screen (... more Queries sub Menu)

3.7.3 Products In the essential drugs list

- Activating the “Products In the EDL” button displays, in spreadsheet format, the list of all approved application records in the database that are listed as essential drugs in the country.

Is pro	Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN	Pharmac
<input checked="" type="checkbox"/>	1	3M SANTE	3M SANTE	ASPIRINE PH 8TM 500MG	ASPIRINE PH 8TM 500MG	
<input checked="" type="checkbox"/>	1440	EUROMED	EUROMED LABC	0.9% SODIUM CHLORIDE	0.9% SODIUM CHLORIDE	INFUSION
<input checked="" type="checkbox"/>	1441	EUROMED	EUROMED LABC	0.9% SODIUM CHLORIDE	0.9% SODIUM CHLORIDE	INFUSION
<input checked="" type="checkbox"/>	863	CHONGWAE	CHONGWAE PH	10 % DEXTROSE	10 % DEXTROSE	INFUSION
<input checked="" type="checkbox"/>	3982	THAI OSUT	THAI OSUTKA	10% DEXTROSE	10% DEXTROSE	INFUSION
<input checked="" type="checkbox"/>	3983	THAI OSUT	THAI OSUTKA	10% DEXTROSE INJ.	10% DEXTROSE INJ.	INFUSION
<input checked="" type="checkbox"/>	1442	EUROMED	EUROMED LABC	10% DEXTROSE IN WATER	10% DEXTROSE IN WATER	INFUSION
<input checked="" type="checkbox"/>	1443	EUROMED	EUROMED LABC	10% DEXTROSE IN WATER	10% DEXTROSE IN WATER	INFUSION
<input checked="" type="checkbox"/>	4448	YF CHEMIC	YF CHEMICAL	10% GLUCOSE INJ.	10% GLUCOSE INJ.	INFUSION
<input checked="" type="checkbox"/>	864	CHONGWAE	CHONGWAE PH	20 % MANNITOL	20 % MANNITOL	INFUSION
<input checked="" type="checkbox"/>	865	CHONGWAE	CHONGWAE PH	30% DEXTROSE INJ.	30% DEXTROSE INJ.	INFUSION

- Each row represents one approved product on file in the essential drugs list and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).

- To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.4 Products by Ingredients

- A dialogue box appears on the screen after clicking the “Products By Ingredients” button.

- Enter a known ingredient of a product. If unsure of the exact spelling of the ingredient, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.
- Click the “OK” button to start the search process.
- The data of all approved product records, in spreadsheet format, based on the name of ingredient specified is shown on the screen.

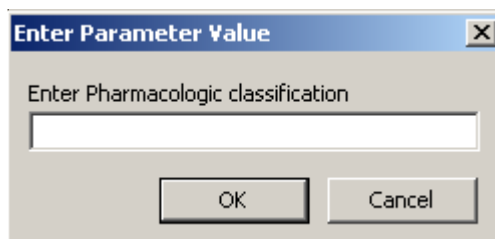
Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN	Phai
399	BINH DINH F	BINH DINH PHAR	PARACETAMOL 500 MG	PARACETAMOL 500 MG	
650	CPE	CPE	PARACETAMOL CPE 100MG	PARACETAMOL CPE 100MG	TABI
651	CPE	CPE	PARACETAMOL CPE 500MG	PARACETAMOL CPE 500MG	TABI
652	CPE	CPE	PARACETAMOL 500MG	PARACETAMOL 500MG	
653	CPE	CPE	PARACETAMOL CPE 100MG	PARACETAMOL CPE 100MG	TABI
654	CPE	CPE	PARACETAMOL CPE 500MG	PARACETAMOL CPE 500MG	TABI
740	CADILA HE	CADILA HEALTH	PARACETAMOL 500 MG TAB.	PARACETAMOL 500 MG TAB.	
1049	CREAT	CREAT	PARACETAMOL 500 MG	PARACETAMOL 500 MG	
1050	CREAT	CREAT	PARACETAMOL 500MG	PARACETAMOL 500MG	
1571	FLAMINGO	FLAMINGO PHA	PARACETAMOL 500MG	PARACETAMOL 500MG	
2219	LARK LAB	LARK LABO	PARACETAMOL 500MG TAB.	PARACETAMOL 500MG TAB.	
2337	LYKA LAB	LYKA LABS	PARACETAMOL 500MG	PARACETAMOL 500MG	

- Each row represents one approved product on file based on the name of the manufacturer criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
- Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
- Search the records based on the searching and filtering methodologies (Under the “**Searching / Filtering Records**” topic)

8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

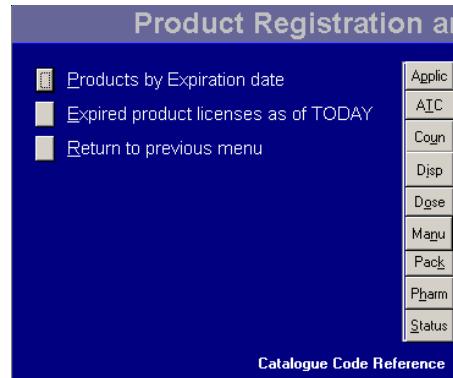
3.7.5 Products by Pharmacologic Classification

1. A dialogue box appears on the screen after clicking the “Products By Pharmacological Classification” button.
2. Enter a pharmacological classification description. If unsure of the exact spelling of the pharmacology classification, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.



3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format, based on the specified pharmacological classification is shown on the screen.
5. Each row represents one approved product on file based on the pharmacological classification criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic)
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

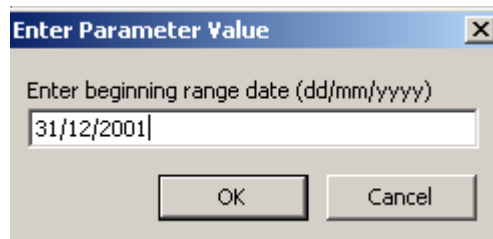
3.7.6 Products by Registration Dates



3.7.6.1 Current Registration License

1. A dialogue box appears on the screen after clicking the “Current Registration License” button.
2. You are expected to enter two dates – a beginning and an end dates that encloses the group or groups of approved product records based on the current registration license date field.

(NOTE: Date format is of the form: dd/mm/yyyy)



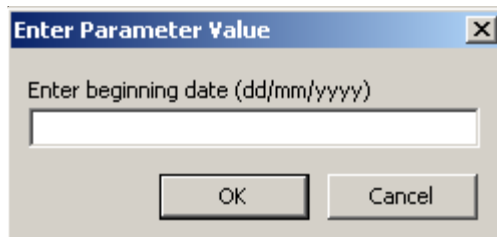
3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format, based on the current registration date criteria you have specified is shown on the screen.

MA issue c	Application#	Applicant / M	Manufacturer	Brand / Trade Name	INN
02/01/2000	1430	ETHYPHAF	ETHYPHARM	DELASMIL SR CAPS 50MG	DELASMIL SR CAPS 50MG
02/01/2000	4287	UPSA	UPSA	PRODAFALGAN 2 G INJ.	PRODAFALGAN 2 G INJ.
02/01/2000	1429	ETHYPHAF	ETHYPHARM	DELASMIL SR CAPS 400MG	DELASMIL SR CAPS 400MG
02/01/2000	4288	UPSA	UPSA	SKENAN LP 100MG	SKENAN LP 100MG
02/01/2000	4289	UPSA	UPSA	SKENAN LP 10MG	SKENAN LP 10MG
02/01/2000	4290	UPSA	UPSA	SKENAN LP 30MG	SKENAN LP 30MG
02/01/2000	1428	ETHYPHAF	ETHYPHARM	DELASMIL SR CAPS 200MG	DELASMIL SR CAPS 200MG

5. Each row represents one approved product on file based on the current registration date criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.6.2 Historical (Range)

1. A dialogue box appears on the screen after clicking the “Historical (Range)” button.



2. You are expected to enter two dates – a beginning and an end date that enclose the group or groups of registered products based on the historical data field. For example, if you want to list all registered products during the year 1998 one will enter 01/01/1998 as the beginning date and 31/12/1998 as the end date value.

(NOTE: Date format is of the form: dd/mm/yyyy)

3. Click the “OK” button to start the search process.
4. The data of all approved product records, in spreadsheet format, based on the historical date criteria of the product you have specified is shown on the screen.
5. Each row represents one approved product on file based on the historical date of the product criteria set and each column representing the data for that field item (e.g. Application #, Brand Name, etc.)
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” keys to move a set of records one screen full up or down at a time.

7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.6.3 Return to Previous Menu

1. Clicking the “Return to Main Menu” button brings you back to the previous menu selection screen.

3.7.7 Products by Status

1. A dialogue box appears on the screen after clicking the “Products By Status” button.
2. Enter a status code of a product. If unsure of the status codes, make use of the wild card “*” symbol to represent any letter or group of letters in the dialogue box field.

3. Click the “OK” button to start the search process.
4. The data of all APPROVED product records, in spreadsheet format, based on the status specified is shown on the screen.

Application#	Activity/Status	Applicant / MA Holder	Manufacturer	Brand / Trade
3814	TEMPORARY LI	SYNTHELABO	SYNTHELABO	DOGMATIL 50MG
722	TEMPORARY LI	CADILA HEALTHCARE	CADILA HEALTHCARE	DOMPERIDON 10 ME
2733	TEMPORARY LI	PT DANKOS LABORATOIRES TBK	PT DANKOS LABORATOIRES TBK	DOMETIC 10MG
4114	TEMPORARY LI	UNICHEM	UNICHEM	DOMADOL * 50 50M
4113	TEMPORARY LI	UNICHEM	UNICHEM	DOMADOL * 100 100
4112	TEMPORARY LI	UNICHEM	UNICHEM	DOMADOL 50MG
1939	TEMPORARY LI	INNTECH INTERNATIONAL	INNTECH INTERNATIONAL	DOLOTEC @ 500MG
4042	TEMPORARY LI	TORRENT	TORRENT	DICLOMAX-50 TABLE

5. Each row represents one approved product on file based on the product status criteria set and each column represents the data for that field item (e.g. Application #, Brand Name, etc.).
6. Use the “Up-Down” arrow keys on the computer keyboard to move one record up or down or use the “PgUp-PgDn” to move a set of records one screen full up or down at a time.
7. Search the records based on the searching and filtering methodologies (Under the “Searching / Filtering Records” topic).
8. To close the spreadsheet window on your screen, click the “x” button found on the top right portion of the spreadsheet.

3.7.8 Return to Previous Menu

1. Clicking the “Return to Main Menu” button brings you back to the previous menu selection screen.

3.8 Return to Main Menu

1. Clicking the “Return to Main Menu” button brings you back to the Drug Registration Main Menu.

4. PREPARE TO PRINT FORM1

This menu selection allows you to print the Application Form (two pages), Routing Slip (one page) and the Checklist of Requirements (one page). The forms will again be displayed in *MSWord*[™] and can be printed from the *MSWord*[™] program.

The screenshot shows a Microsoft Word window titled 'FORM1 - Microsoft Word'. The document is a form titled 'APPLICATION FOR DRUG REGISTRATION'. The form is divided into three main sections:

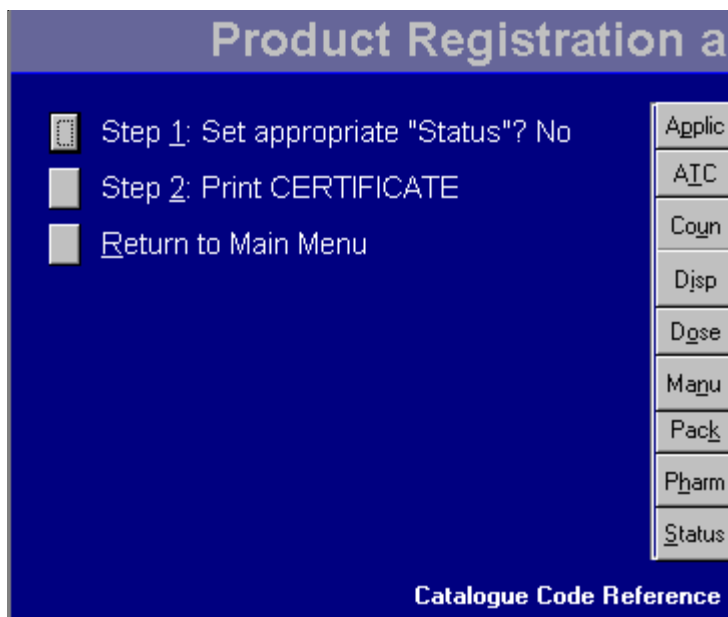
- PART I. INFORMATION (APPLICANT):** Includes fields for Name, Address, Telephone, Fax, and Contact person.
- PART II. MANUFACTURER INFORMATION:** Includes fields for Name, Address, Telephone, Fax, and Contact person.
- PART III. INFORMATION (PRODUCT):** Includes a table for Active Ingredients.

The table for Active Ingredients has the following structure:

Name		Active Ingredients	
	ID#	Name	ID#
1		4	
2		5	
3		6	

5. PREPARE DRUG REGISTRATION CERTIFICATE

This submenu is an office automation aid to print the Drug Registration Certificate. This will make printing of the certificates more efficient and less time consuming. Typographical mistakes will also be limited to the errors entered in the forms. This selection will be performed in two steps. Follow the steps in the order they are presented below.



5.1 Step 1. Set appropriate “Status?” number

This first step in the preparation of the Drug Registration Certificate is to check the status of the product record. Setting the status to “Print certificate” enables you to print the registration certificate for the product. After selecting this button, the “Change Status Form” is presented. Position the cursor on the Application No. field and press the “binoculars” icon to bring up the status of the product. The “Brand Name” and “Dosage Form” of the product is displayed together with the application number for you to confirm that the product you are referring to is indeed the one you want.

Change STATUS Form

Change Status FORM

Application No: 00001

Lic. Owner: FACTORY NO. 2

Manufacturer: FACTORY NO. 2

Brand Name: DEXTROSE&NACL TL

Dosage Form: INFUSION

Applied: []

Reg.#: 00012016/01

Reg. date: 07-Jul-01

Expiry: 06-Jul-06

Activity: PRINT IMPORT CERTIFICATE

Note: Double click the Applied field to change status

Record: 1 of 2612

Set the mouse on the “Applied” field and double-click the field. The fields in the form should turn green. This allows you to change data in any of the green-colored fields. Go further down and pull down the selection button on the “Activity” field. A list of all the available “status/activities” is listed.

Applied: [/ /]


Reg.#: 00510167/93

Reg. date: 04-May-93

Expiry: 03-May-98

Activity: CERTIFICATE EXPIRED

Note: Double click the Applied field to change status

You can also change a group of records of the same current status to another status by clicking on the  icon on the form. A window asking you to enter a status code is shown. Look up the status codes on the quick reference guide on the product registration main menu.

5.2 Step 2. Print Certificate

The second step in the printing of the certificates will open the *MSWord*[™] program and then load the Drug Registration Certificate template. This step will open a file containing all the products whose “Activity/Status” is or has been changed to “Print Certificate.” This will load the data of the products into the template. You are then ready to start merging the data with the

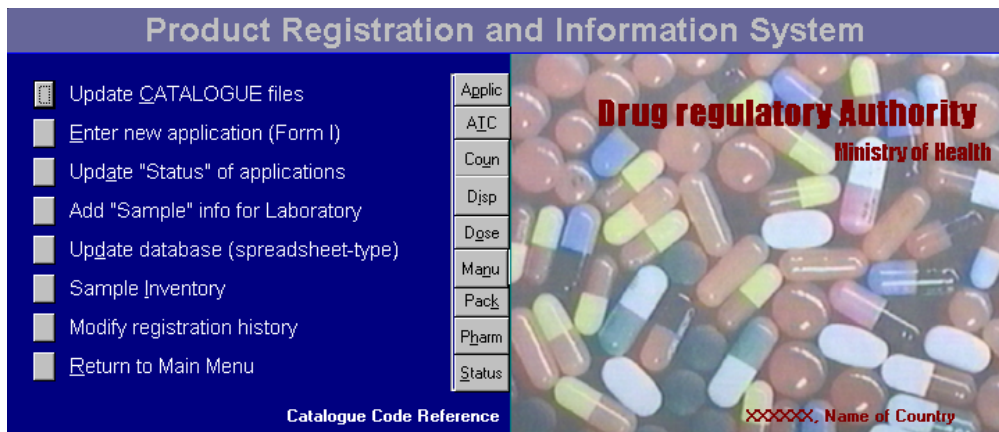
drug registration certificate template. Click the “merge icon” on the menu and a window asking you to start the merge will appear. Press “merge” on the *MSWord*[™] menu bar and the merge process will start. The different Drug Registration Certificates will be shown on your computer screen. You can now proceed by printing the Drug Registration Certificates as you would any other *MSWord*[™] document. The number of copies you wish to print can be set on the File-Print menu of the *MSWord*[™] program. Press the “printer” button to start the printing of the certificates. Once done, press the “X” in the upper right corner of the window or exit Microsoft Word without saving the documents.

5.3 Return to Main Menu

Selecting this button brings you back to the product registration system main menu.

6. UPDATE DATABASES

This section updates the data in the product registration system.

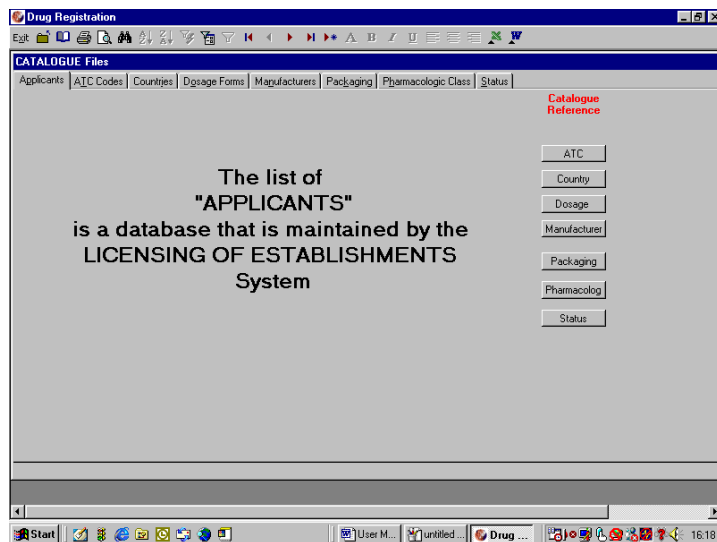


6.1 Update CATALOGUE files

There are eight catalogue files used in the product registration system. Each table contains the needed data used in the database. The catalogue files ensure uniformity when entering data into the system. Without these catalogue tables, variable data entry can be expected, and which can lead to inaccuracies when retrieving data.

For example, without the catalogue tables, the dosage form tablets can be entered in various different ways e.g. tab, tabs, tablet, tablets, tab., tabs.


1. Selecting the “Update Catalogue Files” button brings up the Update catalogue file form. The first tabbed catalogue, “applicants,” is shown. The applicants catalogue file cannot be updated from the Product Registration System.



Because the list of applicants is “shared” information from the Licensing of Establishments System, the product registration system cannot update this catalogue file. It can only be updated from the Licensing of Establishments System.

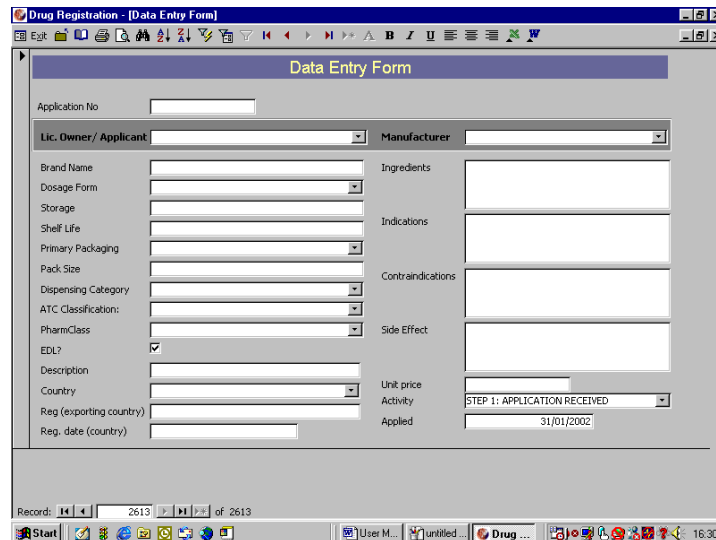
There are seven catalogue tables: ATC classification; Countries; Dosage Forms; Manufacturers; Packaging; Pharmacologic classification; and Status/Activity. The tabbed catalogues are arranged alphabetically.

2. Position the mouse pointer on the flap of the tab and the catalogue table of your choice is ready for data entry. You will need to add an item when the item that you are entering in Form 1 will not be accepted by the system because it is not known to the system i.e. it is not in the catalogue tables.

3. Use the add button  to add new catalogue data. Use the “Pgup-Pgdn” keys to scroll down the list.
4. After updating close the form by clicking on the “x” icon on the top right of the form.

6.2 Enter DATA for new application (Form 1)

1. Before entering the data for a new application, check that the entries needed by the new application are in the catalogue files. After updating the catalogue tables.
2. You can now start data entry. Always enter a unique number for a new application. Applications have been entered sequentially starting with 00001, 00002,05000....
3. The form is divided into four parts. This is similar to the form that was submitted by the applicant. Parts one and two are the applicant and manufacturer information respectively. Part three is the product information while Part four is the importation / status information. Most of the fields require that data should be entered or else the record will not be accepted by the database.



The screenshot shows a software window titled "Drug Registration - [Data Entry Form]". The main area is a form with the following fields and sections:

- Application No:** Text input field.
- Lic. Owner/ Applicant:** Dropdown menu.
- Manufacturer:** Dropdown menu.
- Brand Name:** Text input field.
- Dosage Form:** Dropdown menu.
- Storage:** Text input field.
- Shelf Life:** Text input field.
- Primary Packaging:** Dropdown menu.
- Pack Size:** Text input field.
- Dispensing Category:** Dropdown menu.
- ATC Classification:** Dropdown menu.
- PharmClass:** Dropdown menu.
- EDL?:** Checked checkbox.
- Description:** Text input field.
- Country:** Dropdown menu.
- Reg. (exporting country):** Text input field.
- Reg. date (country):** Text input field.
- Ingredients:** Text area.
- Indications:** Text area.
- Contraindications:** Text area.
- Side Effect:** Text area.
- Unit price:** Text input field.
- Activity:** Dropdown menu with value "STEP 1: APPLICATION RECEIVED".
- Applied:** Date field with value "31/01/2002".

At the bottom, a status bar indicates "Record: 2613 of 2613". The Windows taskbar at the bottom shows the Start button, system tray, and open applications including "User M...", "Untitled...", and "Drug ...". The system clock shows "16:30".

6.3 Update “Status” of applications

1. This will be the submenu selection you will use when you want to print a certificate, send the application for the Drug Control Committee, and send samples to laboratory.


The screenshot shows a software window titled "Change STATUS Form". The window contains several input fields and a button. The fields are: Application No (00001), Lic. Owner (FACTORY NO. 2), Manufacturer (FACTORY NO. 2), Brand Name (DEXTROSE&NACL 1L), Dosage Form (INFUSION), Applied (empty), Reg # (00012016/01), Reg date (07-Jul-01), Expiry (06-Jul-06), and Activity (PRINT IMPORT CERTIFICATE). A button labeled "Change By Group status" is located to the right of the Applied field. Below the Activity field, there is a note: "Note: Double click the Applied field to change status". At the bottom of the window, the status bar indicates "Record: 1 of 2612".

2. When you want to group a batch of applications such as sending a group for the Drug Control Committee deliberation, you simply change the status of the group of applicants to a particular activity or status. As soon as you have done that, you are ready to print a report.
3. The same selection is used after evaluation is performed. When the application is referred to the Drug Registration Committee for deliberation, the application gets a new status by changing the status using this form. After the Drug Registration Committee deliberations, a new status is again assigned. When final action status is reached, the application has a final status that is either approved, rejected or abeyance, depending on the outcome of the deliberations by the Drug Registration Committee.
4. Once the application is approved, a registration number, date of registration and expiration date are assigned to the application using this same form.
5. The date of expiration was intentionally not pre-computed to provide for flexibility as to the number of years a product certificate will be given an expiration date.

6. Navigation tools are provided in the status form. A “status reference” is built into the form so that when you have forgotten a status code, you simply click on the status reference button from there. Also in the form is a button that will display the records of a particular status. This will allow the user to know the status of records.




6.4 Add “Sample” information for Laboratory

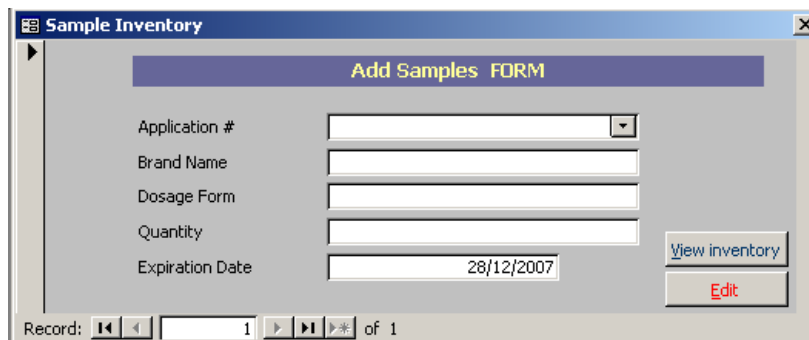
In regulatory agencies with laboratory facilities, you wish to track down the list of samples that have been sent to the laboratory for testing. This menu selection will give you the information of the samples that have so far been sent to the laboratory with the corresponding quantity and expiration dates. Follow the instructions below to enter a sample to be sent for testing.

1. Enter the application number corresponding to the application number or routing slip of the samples. Use the  to enter a sample sent to laboratory.
2. Position the cursor on the application number field. A list of applications numbers will scroll down.
3. Enter the number of samples that will be sent and the expiration date of the samples. Exit by clicking on the exit (door) button.
4. You can view the report containing the products for analysis that will be sent to the laboratory by going to the print reports submenu under the submenu “List of Samples for Analysis.” The list of products in the report was positioned in the middle of the document. This was intentionally done so that a pre-printed document with the DRA header can be used. The format of the document can also be changed using MSWord™ to suit user preference.

6.5 Sample Inventory

This menu selection will give you an inventory of all samples and enables you to track down their expiration dates.

To enter data of a sample you wish to add in the inventory, press the  button and a blank “Add samples form” screen is presented. Go to the application# field and press the  button and the list of all the routing slip numbers is shown. Enter the routing slip number of the sample you wish to enter in the inventory list. Enter the quantity and the expiration date of the sample. Save the sample by moving the record forward or backward by pressing any of the  buttons at the bottom of the form.



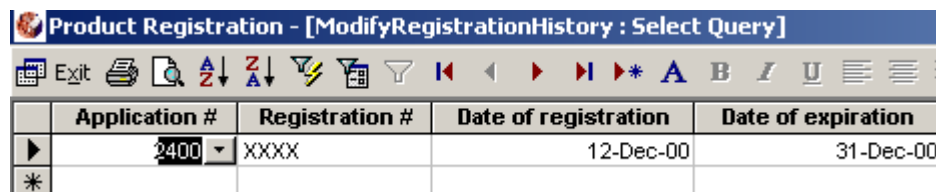
The screenshot shows a window titled "Sample Inventory" with a sub-header "Add Samples FORM". The form contains the following fields:

- Application #: A dropdown menu.
- Brand Name: A text input field.
- Dosage Form: A text input field.
- Quantity: A text input field.
- Expiration Date: A text input field containing "28/12/2007".

At the bottom right of the form are two buttons: "View inventory" and "Edit". At the bottom left, there is a record navigation bar showing "Record: 1 of 1" with navigation icons.

6.6 Modify Registration History

This selecting this button allows you to modify the registration history of products already in the registry. This option is provided in order to update the registration status of products that have been entered.



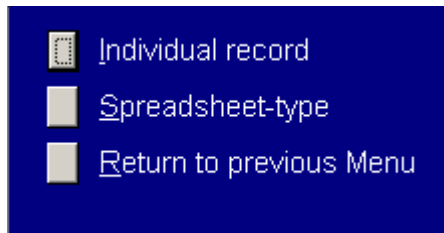
The screenshot shows a window titled "Product Registration - [ModifyRegistrationHistory : Select Query]". It contains a table with the following data:

	Application #	Registration #	Date of registration	Date of expiration
▶	2400	XXXX	12-Dec-00	31-Dec-00
*				

1. On the application # field, enter the application number of the product.
2. Enter the registration number, the registration date and expiration date of the product.
3. Press “exit” when finished.

6.7 Edit Records

This option allows you to edit the data of products in already in the registry.



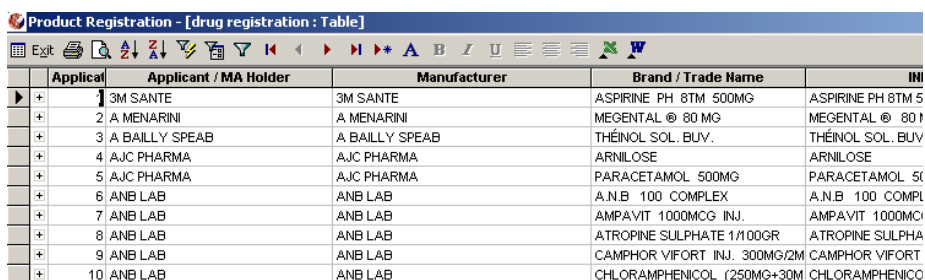
6.7.1 Individual record

The form below is the complete data of one product in the registry. To edit the product information, enter the details on the fields. Use the searching techniques described in this manual in order to retrieve a product of interest.

Edit Drug registration DATA			
Application No	Applicant / MA Holder	Manufacturer	Brand Name
3M SANTE	3M SANTE	3M SANTE	ASPIRINE PH 8TM 500
INN	Dosage Form		
ASPIRINE PH 8TM 500MG			
Storage			
Shelf Life	Primary Packaging	Pack Size	
		B/5 X 10 CP.	
Dispensing Category	ATC Classification	PharmClass	EDL?
PRESCRIPTION ONLY		ANALGESICS & ANTI-INFLA	<input checked="" type="checkbox"/>
Description			
SDASDF			
Country	Registration No (importing country)	Date of registration (importing country)	
FRANCE	31/12/2002	23/12/2002	
Ingredients			
ASPIRINE PH 8TM 500MG			
Indications			
ASDFS			
Contraindications			
ASDFS			
Side Effect			
AFASD			

6.7.2 Spreadsheet-type

Making this choice opens a list of products in the registry in spreadsheet format. Use the searching methods described in this manual to go to a particular product of interest.



	Applicant	Applicant / MA Holder	Manufacturer	Brand / Trade Name	INI
+	1	3M SANTE	3M SANTE	ASPIRINE PH. 8TM. 500MG	ASPIRINE PH.8TM 5
+	2	A MENARINI	A MENARINI	MEGENTAL ® 80 MG	MEGENTAL ® 80 I
+	3	A BAILLY SPEAB	A BAILLY SPEAB	THÉINOL SOL. BUY.	THÉINOL SOL. BUY
+	4	AJC PHARMA	AJC PHARMA	ARNILOSE	ARNILOSE
+	5	AJC PHARMA	AJC PHARMA	PARACETAMOL 500MG	PARACETAMOL 50
+	6	ANB LAB	ANB LAB	A.N.B 100 COMPLEX	A.N.B 100 COMPL
+	7	ANB LAB	ANB LAB	AMPAVIT 1000MCG INJ.	AMPAVIT 1000MCG
+	8	ANB LAB	ANB LAB	ATROPINE SULPHATE 1/100GR	ATROPINE SULPHA
+	9	ANB LAB	ANB LAB	CAMPHOR VIFORT INJ. 300MG/2M	CAMPHOR VIFORT
+	10	ANB LAB	ANB LAB	CHLORAMPHENICOL (250MG+30M)	CHLORAMPHENICO

1. This menu selection uses the familiar interface of Microsoft Excel. When correcting a batch of records in this format, the Excel program is appealing.
2. On this screen, data can be edited or updated and records can even be deleted. This screen is provided to facilitate data entry and searching.

6.7.3 Return to Main Menu

Select this to return to the main menu.

7. Exit

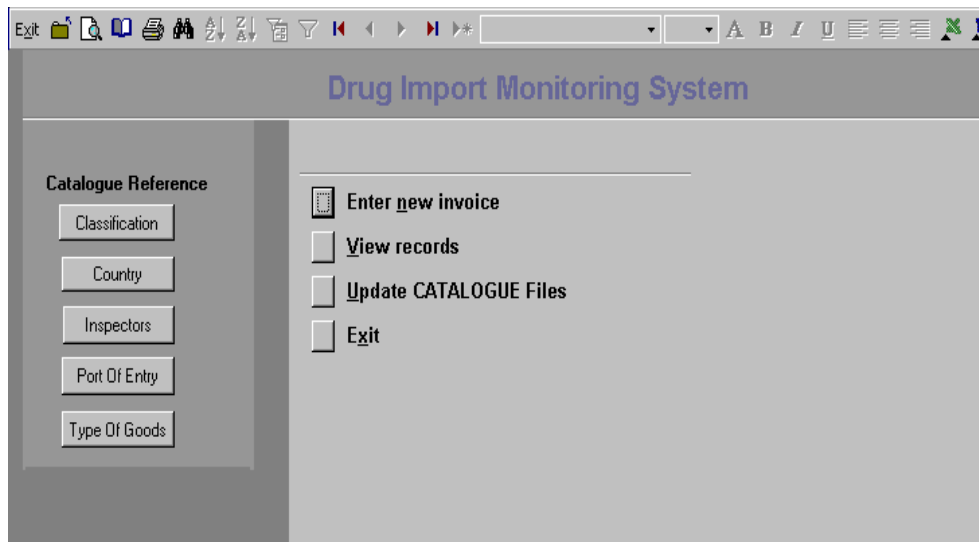
This closes the database and exits the Product registration subsystem.

DRUG IMPORT MONITORING SUBSYSTEM

MAIN MENU

The Drug Import Monitoring Subsystem tracks down the importations of drugs based on the invoice documents submitted by importers. Importers who are not registered as duly registered establishments with the Licensing of Establishments System cannot transact an importation. Likewise, only products that are registered and listed in the Product Registration System can be entered.

The main menu window has several selections for entering new invoices, viewing and printing management reports and updating the Import Monitoring System catalogue files. On the left side of the Main Menu are the quick reference catalogue file buttons.



1. Enter new invoice
 1. Activating this selection will open the invoice data entry form. The form is organized into two parts. At the top portion is invoice information and at the lower portion are the transaction details. The transaction details outline the information about the drug being imported.

- The subsystem checks two very important data: the applicant and the product. The applicant (also importer) should be a registered importer listed in the Licensing of Establishments Subsystem. Similarly, the product being imported should be a registered product and should be listed in the Product Registration System. If neither one is registered, then the importation should not be allowed.

Invoice

Ref# []

Invoice # [123] Inspector [THAVY ATHSAYAVONG]

Classification [DONATION] Remarks [THE QUICK BROWN FOX JUMPS OVER THE LAZY DOG]

Applicant [RAINIER COMPANY]

Date of Importation [04-May-01]

Port of Entry [BOTEND]

List of prohibited drugs

Brand Name	Status0	TypeOfGoodsCode	Manufacturer	CountryID	Manufactu	Expiration	Lot#	Batch#	Quant
RENITEC 20	<input checked="" type="checkbox"/>	NARCOTIC	XXX	CHINA	01-Jan-01	01-Jul-05	XXX	XXX	25X2
CEPHALEXI	<input checked="" type="checkbox"/>	DRUG	XYZ	SWITZERLAND	01-Jan-01	31-Dec-05	234	123BC	50 BOXI
SAMOXIN	<input checked="" type="checkbox"/>	NARCOTIC	SSS	THAILAND	04-May-01	31-Mar-03	DDD	34R5	4 BOXE
RANOXYL I	<input checked="" type="checkbox"/>	PSYCHOTROPIC	SSS	TAIWAN, CHINA	03-Mar-99	31-Dec-04	12345	998-90A	3 AMPU

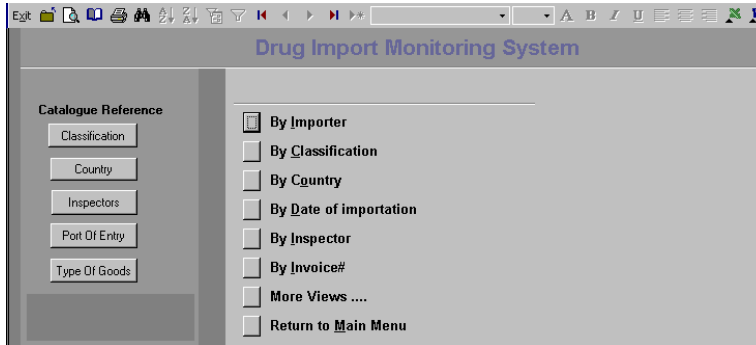
Record: 1 of 4

Record: 1 of 5

- A button that opens the list of prohibited drugs is provided on the same form as a guide for the type of goods (i.e. whether the product being imported is classed as a narcotic, psychotropic or precursor chemical) being imported.
- Applicants and products must both be registered entities with the regulatory authority before importation is authorized and subsequently monitored in this subsystem.

2. View Records Menu


There are several options to view the contents in this database. Shown below are the available choices for viewing.



2.1 By importer

This option provides the list of importations made by importers (also called the applicant or product license holder). The list is alphabetically arranged according to the name of applicant or company. The second column (see below) shows the number products, weight in kilograms and the total importations made.

2.2 By classification

Choosing this option lists the products imported according to the classification of the product. Examples of importation classification include: commercial use; clinic use only; donated product; and hospital use only. The second column shows the number of products in the classification category and the weight and the total value of the product in the classification. Position the mouse in any portion on the form and the details of the importations will be shown. Close the windows one by one by clicking the  "close button" on the top menu.

Summary by CLASSIFICATION

Classification	# of products	Weight(Kg)	Total (USD)
▶ DONATION	7	1,230.00	18,354.76
HOSPITAL USE ONLY	3	115.00	17,593.00
COMPASSIONATE USE	1	90.00	9,877.00

Record: 1 of 3

Click anywhere on form to see details Total

2.3 By country

Using this option opens a window that shows all the importations by country and the number of products imported by the country. The weight in kilograms and the total value are also reflected. Double click on any part of the form and the details will be shown.


Summary by COUNTRY

Country	# of products	Weight(Kg)	Total (USD)
▶ ARGENTINA	1	45.00	799.00
BRAZIL	1	450.00	339.78
CHINA	1	50.00	2,100.00
INDIA	1	30.00	2,000.00
PHILIPPINES	1	90.00	3,456.00
SWITZERLAND	1	500.00	3,450.00
THAILAND	2	140.00	11,894.00
TAIWAN, CHINA	1	10.00	3,008.98
UNITED STATES OF AM	2	120.00	18,777.00

Record: 1 of 9

Click anywhere on form to see details Total

2.4 By date of importation

Viewing the importations by date is the most useful as far as drug importation monitoring is concerned. Most queries on drug importations are date-related so this will be the most widely used feature in the drug import monitoring. There will be varied queries from the drug regulatory staff. The data presented in the tables will have to be manipulated using MSEXel in order to answer the more complex queries. The dataset in this viewing option can be exported using the  (MSEXel) button provided on the top of the menu bar. Once exported, the data can be summarized or manipulated using various MSEXel techniques.

Clicking on any part of the form will display the importation details by date. Again, exporting the data to MSEXel provides a way to analyze the data. Staff training should be provided for maximum benefit.

Summary by DATE OF IMPORT				
MONTH				
Month	# of products	Weight (Kg)	Total (USD)	
August 1999	1	90.00	9,877.00	
May 2001	4	660.00	12,558.98	
September 1999	1	90.00	3,456.00	
September 2001	5	595.00	19,932.78	

Record: 1 of 4

QUARTER				
Quarter	# of products	Weight (Kg)	Total (USD)	
Q2 2001	4	660.00	12,558.98	
Q3 1999	2	180.00	13,333.00	
Q3 2001	5	595.00	19,932.78	

Record: 1 of 3

YEAR				
Year	Weight (Kg)	# of products	Total (USD)	
1999	180.00	2	13,333.00	
2001	1,255.00	9	32,491.76	

Record: 1 of 2

2.5 By inspector

Activating this option will show all importations by inspector. The list of drug inspectors in the regulatory authority should be entered in the catalogue file under the inspector heading. Once the inspectors' names are in the catalogue file, then entering the inspectors and the products they have inspected is just a click of a button away.

Summary by INSPECTOR				
Inspector	# of products	Weight (Kg)	Total (USD)	
INSPECTOR 1	4	660.00	12,558.98	
INSPECTOR 2	1	90.00	3,456.00	
INSPECTOR 3	2	480.00	2,339.78	
INSPECTOR 4	4	205.00	27,470.00	

Record: 1 of 4

Click anywhere on form to see details

2.6 By invoice number

Viewing importations by invoice number provides a way to look at the summary of product importations by invoice number. The invoices are the source document from where all the data in the drug import monitoring system are taken. The valuation summary is provided. Double click on any part of the form and the importation details per invoice will be shown.

Summary by INVOICE#

Summary of invoice#

Invoice #	# of products	Weight (Kg)	Total (USD)
123	4	660.00	12,568.98
45/89WS	3	115.00	17,593.00
789A/90	1	90.00	9,877.00
ABCE/90	2	480.00	2,339.78
YUR/56E	1	90.00	3,456.00

Record: 1 of 5

Click anywhere on form to see details

2.7 More views ...

Activating this option gives you more ways to view the drug import monitoring database.

Drug Import Monitoring System

Catalogue Reference

Classification

Country

Inspectors

Port Of Entry

Type Of Goods

By Manufacturer
 By Port of Entry
 By Product Name
 By Product Registration Status
 By Type of Goods
 Return to Previous menu

2.7.1 By manufacturer

This option shows all the product importations by manufacturer. The details of products imported by manufacturer are also provided by double clicking on any part of the form.

Summary by MANUFACTURERS

Summary by MANUFACTURER

Manufacturer	# of manufact	Description	# of products	SumOfWeightKg	SumOfUSDPrice
WASDAS	1 1609		1	30.00	2,000.00
MSD	1 2115		1	90.00	3,456.00
ROBAPHARM	1 2365		1	40.00	7,694.00
SLK MANUFACT	1 1429		1	30.00	8,900.00
SSS	1 1490		1	100.00	4,000.00
SSS	1 1789		1	10.00	3,008.98
SSS	1 2320		1	450.00	339.78
XXX	1 1121		1	50.00	2,100.00
XYZ	1 2493		1	500.00	3,450.00
XYZ COMPANY	1 1390		1	90.00	9,877.00
ZUELLIG	1 2434		1	45.00	799.00

Record: 1 of 11

Click anywhere on form to see details

2.7.2 By port of entry

Selecting this option will show all drug importations from where they entered the country or their port of entry. Click on any part of the form and the details of all the products in each of the port of entry are shown.

Summary by PORT OF ENTRY				
Summary by PORT OF ENTRY				
Port of Entry	# of products	Weight (Kg)	Total (USD)	
NYC PORT	4	205.00	27,470.00	
KILOMETER 200	1	90.00	3,456.00	
THAI BOARDER 1	2	480.00	2,339.78	
BOTEND	4	660.00	12,558.98	

Record: 1 of 4

Click anywhere on form to see details

2.7.3 By product name

Selecting this option lists the importations by product name. The trade name is used as the name of product. Click on any part of the form and the details of each product are listed.

Summary by PRODUCT NAME				
Summary by PRODUCT NAME				
Brand Name	CountOfBr	CountOfCl	Sum Of WeightKg	Sum Of USDPrice
RENTEC 20MG	1	1	£50.00	2100
3 BEE VITAMINS	1	1	£90.00	9877
YA BAML OUGHAT	1	1	£30.00	8900
SAMOXIN	1	1	£100.00	4000
D.10.W 10% 500ML	1	1	£30.00	2000
RANOXYL DISTAB 250	1	1	£10.00	3008.98
D.5.W. RINGER'S	1	1	£90.00	3456
PANADOL	1	1	£450.00	339.783
20% GLUCOSE INTRAVENC	1	1	£40.00	7894
RENICO	1	1	£45.00	789
CEPHALEXIN 500MG	1	1	£500.00	3450

Record: 1 of 11

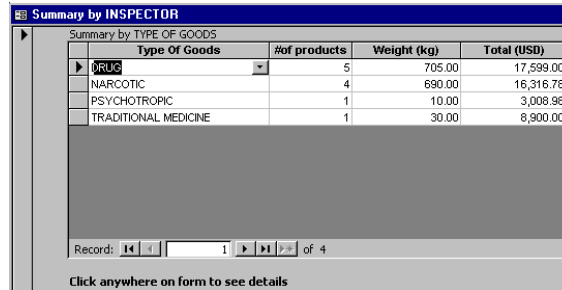
Click anywhere on form to see details

2.7.4 By product registration status

Summary by REGISTRATION STATUS			
Summary by REGISTRATION STATUS			
Is reg?	# of products	Weight (Kg)	Total (USD)
<input checked="" type="checkbox"/>	8	865.00	26,707.98
<input type="checkbox"/>	3	570.00	19,116.78

2.7.5 By type of goods

Selecting this viewing option shows the summary of drug importations by type of goods. The different types of goods will have to be determined by the drug regulatory authority. These are first entered in the catalogue file. Once in the catalogue file, each product being imported into the country can be classified when a request is made. Click on any part of the form and the details of each type of good are shown.



Summary by TYPE OF GOODS

Type Of Goods	#of products	Weight (kg)	Total (USD)
DRUG	5	705.00	17,599.00
NARCOTIC	4	690.00	16,316.78
PSYCHOTROPIC	1	10.00	3,008.98
TRADITIONAL MEDICINE	1	30.00	8,900.00

Record: 1 of 4

Click anywhere on form to see details

2.7.6 Return to previous menu

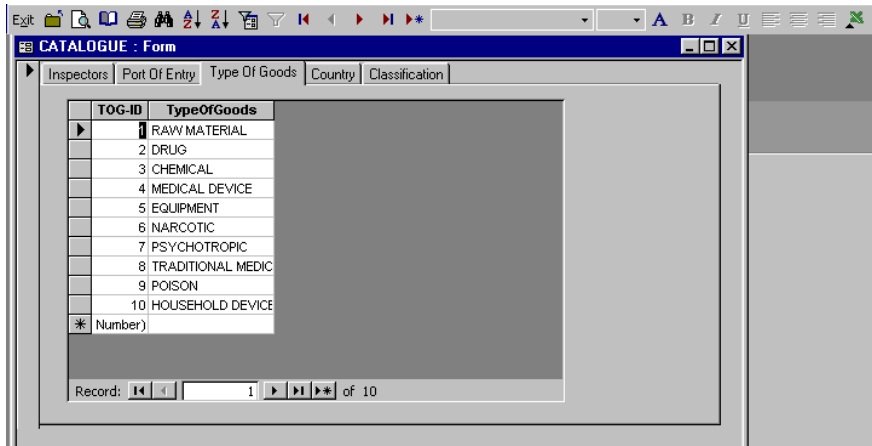
This selection will bring you back to the previous menu.

2.8 Return to Main Menu

Choosing this option brings you back to the Drug Import Monitoring Subsystem Main Menu.

3. Update CATALOGUE FILES

The catalogue files are an important part of each subsystem in the Drug Registration and Information System.



CATALOGUE : Form

Inspectors Port Of Entry Type Of Goods Country Classification

TOG-ID	TypeOfGoods
1	RAW MATERIAL
2	DRUG
3	CHEMICAL
4	MEDICAL DEVICE
5	EQUIPMENT
6	NARCOTIC
7	PSYCHOTROPIC
8	TRADITIONAL MEDIC
9	POISON
10	HOUSEHOLD DEVICE
*	Number)

Record: 1 of 10

4. Exit

This option will close the Drug Import Monitoring Subsystem and bring you back to the Windows desktop.